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Attorney Docket No. 102258.170US3

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: LOSCALZO et al.

Serial No.: 10/692,724

Examiner: To Be Assigned

Filed: October 27, 2003

Group Art Unit: 1651

For: METHODS OF TREATING VASCULAR DISEASES CHARACTERIZED  
BY NITRIC OXIDE INSUFFICIENCY

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

Applicants and their legal representatives hereby make of record on the attached Form PTO-1449 the following publications which are known to them and considered warranting disclosure under 37 C.F.R. §1.56 and 1.97-98. Copies of any cited patents and/or U.S. patent publications are not being submitted in accordance with 37 C.F.R. §1.98(a)(2)(1). However, copies of the cited articles are enclosed.

It is respectfully requested that the information above be expressly considered during the prosecution of this application and that the publications be made of record therein and appear among the "References Cited" on any patent to issue therefrom. In this regard, it is requested that the Examiner initial and return a copy of the enclosed Form PTO-1449 with the next Patent Office Communication.

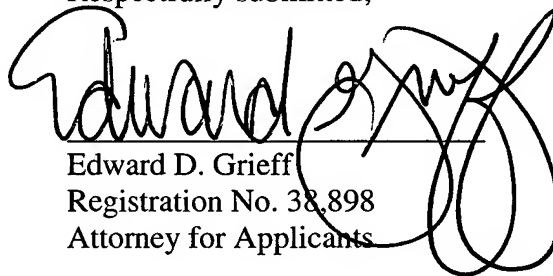
The submission of the publications does not constitute a representation by the Applicants that a search has been made or that no better art exists and does not constitute an admission that the listed publications are material or constitute "prior art." Applicants reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed publications, should one or more of the publications be applied against the claims of the present application.

It is Applicants' belief that the filing of this Information Disclosure Statement precedes the date of the mailing of the first Office Action on its merits, therefore, pursuant to 37 C.F.R. §1.97(b)(3), no fee is believed to be due.

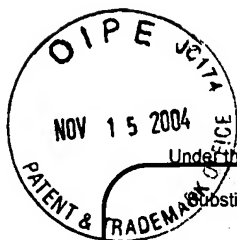
In the event a fee is due, the Commissioner is authorized to charge any fee deficiency or credit any overpayment to Deposit Account No. 08-0219.

Dated: November 15, 2004

Respectfully submitted,

  
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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 3

**Complete if Known**

Application Number	10/692,724
Filing Date	10/27/2003
First Named Inventor	LOSCALZO, et al.
Art Unit	1651
Examiner Name	To Be Assigned
Attorney Docket Number	102258:170US3

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US- 5,760,069	06/02/1998	Lukas-Laskey et al.	
		US- 5,902,821	05/11/1999	Lukas-Laskey et al.	
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**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Sheet

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**Complete if Known**

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10/692,724

Filing Date

10/27/2003

First Named Inventor

LOSCALZO, et al.

Art Unit

1651

Examiner Name

To Be Assigned

Attorney Docket Number

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**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AA	FRANCIOSA, Joseph A., "African-American Heart Failure Trial (A-HeFT): Rationale, Design, and Methodology," Journal of Cardiac Failure, Vol. 8, No. 3, 2002, pp. 128-135	
	AB	YANCY, Clyde W., et al., "Race and the Response to Adrenergic Blockage with Carvedilol in Patients with Chronic Heart Failure," N. Engl. J. Med., Vol. 344, No. 18, May 3, 2001, pp. 1358-1365	
	AC	YANCY, Clyde W., "Heart Failure in African Americans: A Cardiovascular Enigma," Journal of Cardiac Failure, Vol. 6, No. 3, 2000, pp. 183-186	
	AD	EXNER, Derek V., et al., "Lesser Response to Angiotensin-Converting-Enzyme Inhibitor Therapy in Black as Compared with White Patients with Left Ventricular Dysfunction," N. Engl. J. Med., Vol. 344, No. 18, May 3, 2001, pp. 1351-1357	
	AE	PACKER, Milton, et al., "Effect of Carvedilol on Survival in Severe Chronic Heart Failure," N. Engl. J. Med., Vol. 344, No. 22, May 31, 2001, pp. 1651-1658	
	AF	"A Trial of the Beta-Blocker Bucindolol in Patients with Advanced Chronic Heart Failure," N. Engl. J. Med., Vol. 344, No. 22, May 31, 2001, pp. 1659-1667	
	AG	BRAUNWALD, Eugene, "Expanding Indications for Beta-Blockers in Heart Failure," N. Engl. J. Med., Vol. 344, No. 22, May 31, 2001, pp. 1711-1712	
	AH	SCHWARTZ, Robert S., "Racial Profiling in Medical Research," N. Engl. J. Med., Vol. 344, No. 18, May 3, 2001, pp. 1392-1393	
	AI	LEVINE, T. Barry, "Paradoxical Hypertension after Reversal of Heart Failure in Patients Treated with Intensive Vasodilator Therapy," American Journal of Hypertension, Ltd., 1998; 11:1041-1047	
	AJ	ABSTRACTS - Heart Failure 179A, JACC, February 1999	

Examiner Signature	Date Considered
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	AK	KAHN, Jonathan, "How a Drug Becomes "Ethnic": Law, Commerce, and the Production of Racial Categories in Medicine," Yale Journal of Health Policy, Law, and Ethics IV:1 (2004), pp. 1-46	
	AL	PARKER, John D., et al., "The Effect of Hydralazine on the Development of Tolerance to Continuous Nitroglycerin," The Journal of Pharmacology and Experimental Therapeutics, Vol. 280, No. 2, pp. 866-875	
	AM	KALINOWSKI, Leszek, et al., "Race-Specific Differences in Endothelial Function - Predisposition of African Americans to Vascular Diseases," Circulation, June 1, 2004, pp. 2511-2517	

Examiner Signature		Date Considered	
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